

AMENDMENTS TO THE DRAWINGS:

Figure 1 has been amended to remove "SEQ ID NO 1".

REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 15-32 are pending in the present application. Support for new claims 15-32 may be found generally throughout the specification and in the original claims. In particular, support for claims 15-32 may be found in the present specification at page 19, lines 21-29; page 12, lines 6-22; and page 3, lines 27-32. Claims 1-14 have been canceled.

In the outstanding Official Action, the title of the specification was objected to for unnecessarily reflecting what is described in the specification. Accordingly, the title has been corrected.

The specification was also objected to for not complying with sequence rules for applications containing nucleotides and/or amino acid sequences. In particular, the outstanding Official Action cites to Figures 2-4 in the present specification. However, applicants note that Figures 2-4 refer to sequences that are already recited in the sequence listing, or may be found in a public database such as GenBank. Accordingly, applicants respectfully request that the objection be withdrawn.

Figure 1 has been corrected to delete the reference to "SEQ ID NO 1".

The outstanding Official Action requested submission of a substitute oath or declaration. However, 37 CFR 1.63(c) provides that this information may be supplied in an Application Data Sheet. Accordingly, applicants submit herewith a substitute Application Data Sheet.

Claims 1-4, 6-7, 9, 11, and 13 were objected to for referring to a "nucleotide". However, claims 1-4, 6-7, 9, 11, and 13 have been canceled. The new claims recite "nucleic acids" as suggested by the Examiner.

Thus, applicants respectfully request that the objection be withdrawn.

Claims 2, 6, and 11 were rejected under 35 USC §112, second paragraph, for allegedly being indefinite. This rejection is respectfully traversed.

As noted above, claims 2, 6, and 11 have been canceled. Applicants believe that claims 15-32 have been drafted in a manner so as to obviate the indefiniteness rejection.

Claims 1-13 were rejected under 35 USC §101 for allegedly not providing a substantial and specific utility.

In the outstanding Official Action, claims 1-13 were rejected under 35 USC 101 for allegedly not satisfying the utility requirement. This rejection is respectfully traversed.

Applicants respectfully submit that the outstanding Official Action fails to meet its burden in showing that the

present application does not meet the requirements of 35 USC 101.

The standard for imposing a utility rejection is as follows:

"(1) if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (2) the utility is specific, substantial, and credible." See January 2001 USPTO Utility Examination Guidelines.

The Utility Examination Guidelines specifically place on an Examiner who considers an asserted utility "incredible", the following burden:

"a prima facie showing of no specific and substantial credible utility [that] must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention." See January 2001 USPTO Utility Examination Guidelines.

While the Official Action cites to LUCENTINI as teaching that initial studies showing strong disease associations based on statistical correlations do not always result in an actual correlation, applicants note that LUCENTINI only provides a general overview and does not provide any information that relates directly to the claimed invention. Thus, it can not be said that LUCENTINI casts doubt as to the specifically recited utility set forth in the present invention.

The outstanding Official Action also relies on the TAN et al. publication. However, the TAN et al. study concludes that independent replication of the findings within Swedish populations and other ethnic populations is needed (see TAN et al. page 72). Moreover, the article states that there could be a common "founder" effect in a particular race. Thus, applicants believe that it cannot be said that the TAN et al. publication satisfies the burden of showing that a person skilled in the art would not consider the utility asserted by the application as credible, specific and substantial.

Moreover, applicants believe that the TAN et al. study is simply too small to suggest otherwise. Applicants note that TAN et al. draws its conclusions from an unspecified Caucasian population. The study does not attempt to specify the origin of the group, or a control for geographic origin, unlike the data presented in the present application. Hispanic subjects have been studied as controls, but not as cases, which applicants believe invalidates the use of that group. Thus, it is believed that the outstanding Official Action improperly relies on the Hispanic subjects cited in the article.

Applicants do not disagree that there may be differences in the abundance of alleles between different populations. This difference may very well be independent of the effect of the A1 allele on Parkinson's disease, and is a significant factor in the interpretation of the data of TAN et

al. In fact, the TAN et al. publication fails to find an effect of ADH7 mutations in Parkinson's disease because of methodological considerations.

Moreover, applicants note that even if ADH7 mutations might have a relatively minor effect relative to an aggregation of Parkinson's samples from all over the world, they may nevertheless still be vital as to subgroups of patients as very valuable diagnostic tools.

The claimed invention is directed to isolated ADH7 nucleic acid sequences for diagnosing Parkinson's disease and methods of using the isolated ADH7 nucleic acid sequences. Contrary to the assertions of the Official Action, this example does not fall within any of the examples cited in MPEP § 2107.01. Rather, the claims are directed to nucleic acid sequences that have been correlated to a known disease and methods for diagnosing the disease. Accordingly, it is believed that a "real world" is currently claimed and supported by the present disclosure.

Thus, in view of the above, it can not be said that it is more likely than not that the present disclosure does not satisfy the utility requirement.

Claims 1-4 and 6-13 were rejected for allegedly not satisfying the enablement or written description requirement. Applicants believe the present amendment overcomes this rejection.

As noted above, claims 1-4 and 6-13 have been canceled. New claims 15-32 are directed to a ADH7 nucleic acid sequence for diagnosing Parkinson's disease and methods for using the sequences. The claims recite that the nucleic acids trigger Parkinson's disease in a human and/or passes the disease to a later human generation. The sequences themselves are defined by sequence identification numbers.

Thus, the new claims do recite a structure and function so that one skilled in the art would know that applicant was in possession of the claimed invention at the time the invention was filed and how to make and use the claimed invention. Accordingly, applicants believe that the present amendment obviates these rejections.

Claims 1-3, 6-8, and 11-12 were rejected under 35 USC §102(a) as allegedly being anticipated by SAGE-ONO et al., CARSON et al. and NCI-CGAP. Claims 1-2, 6-8, and 11-12 were rejected under 35 USC §102(b) as allegedly being anticipated by ZGOMBIC-KNIGHT et al., YOKOYAMA et al., GLASS et al., KING et al. and MATHEWS et al. Claims 7-8 were rejected as allegedly being unpatentable over GLASS et al. in view of KING et al. Claims 9-10 were rejected under 35 USC §103(a) as allegedly being unpatentable over ZGOMBIC-KNIGHT et al., YOKOYAMA et al., GLASS et al., KING et al., MATHEWS et al., SAGE-ONO et al., CARSON et al. and NCI-CGAP. Applicants believe the present amendment overcomes these rejections.

As noted above, claims 1-13 have been canceled. Applicants believe that the above-identified publications, alone or in combination with each other, fail to disclose or suggest the claimed invention. As noted above, the new claims are directed to isolated ADH7 nucleic acid sequences for diagnosing Parkinson's disease and methods of using the sequences. Applicants believe that none of publications, alone or in combination with each other, teach diagnosing Parkinson's disease with the recited sequences.

As to the ZGOMBIC-KNIGHT et al. publication, applicants note that the present specification at page 4 teaches that the publication describes SEQ ID NO: 1 as being encompassed within the wild-type sequence. Accordingly, it has not been shown that the sequence is associated with Parkinson's disease.

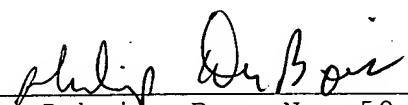
Thus, in view of the above, applicants respectfully request that the rejections be withdrawn.

In view of the present amendment and the foregoing remarks, it is believed that this application has been placed in condition for allowance. Reconsideration and passage to issue on that basis is accordingly earnestly solicited.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following items:

- substitute Application Data Sheet
- replacement drawing sheet for Figure 1